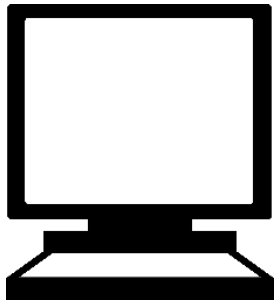
U.S. FOOD & DRUG ADMINISTRATION

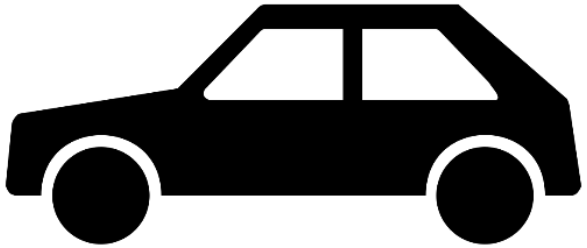
CDER's Quality Management Maturity Program

FDA/CDER/OPQ/OQS

Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.





Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.


Patients expect safe and effective
medicine with every dose they take.

Pharmaceutical quality is

consistently meeting standards that ensure every dose is safe and effective, free of contamination and defects.


It is what gives patients confidence
in their *next* dose of medicine.

Presentation Outline

1. Office of Quality Surveillance
2. Quality Management Maturity

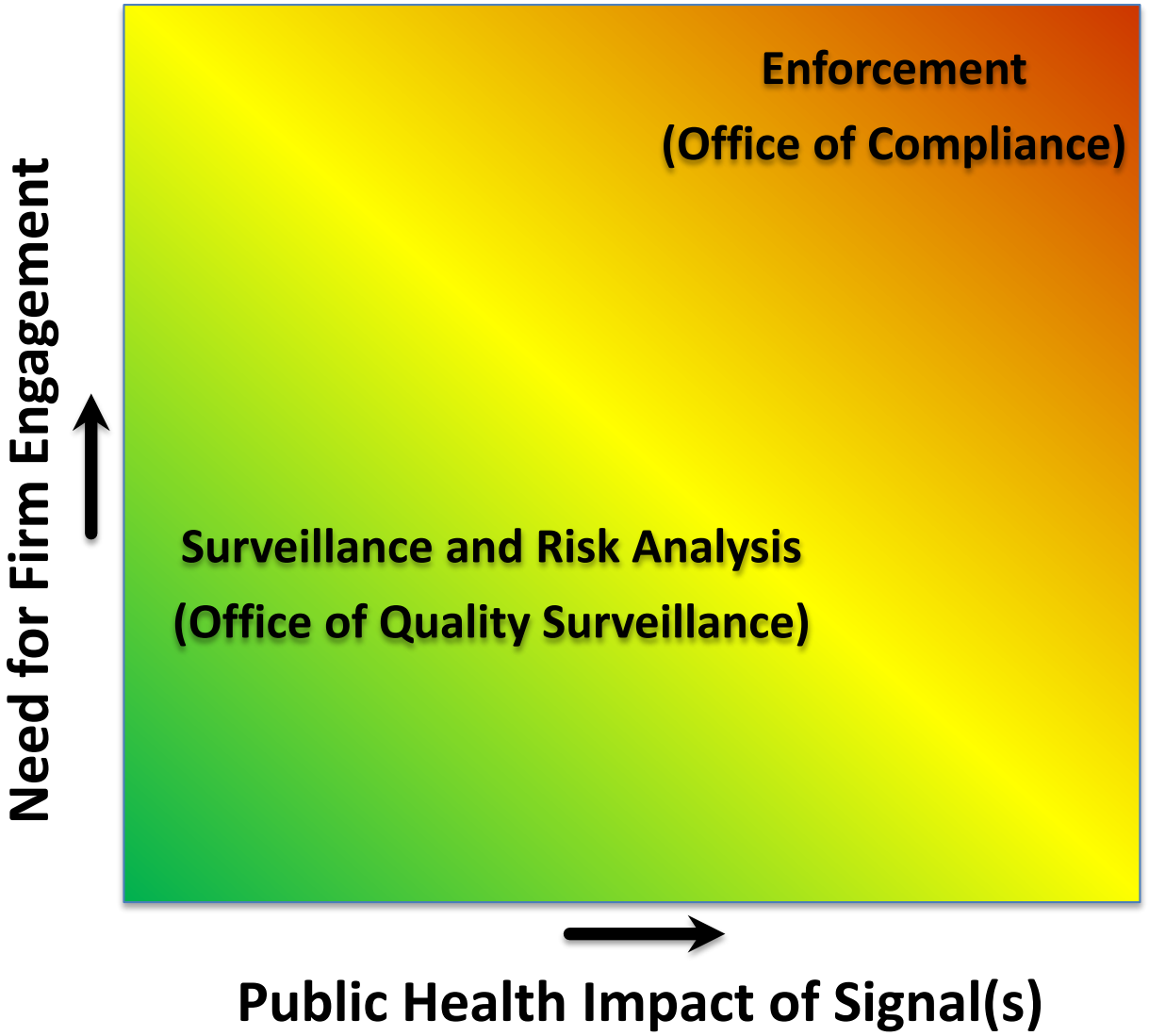
Office of Quality Surveillance

CDER/OPQ'S Office of Quality Surveillance

Office of Quality Surveillance

- Monitors quality and manages information about CDER-regulated sites and products manufactured
- Uses intelligence collected and analytics to make data-driven decisions that can reduce risk to patients
  - Frequency and prioritization of sites for CGMP inspections
  - Human drug surveillance sampling programs
  - Site engagement
  - Quantitate the state of quality
- Proactively identify potential quality signals and trends before serious quality problems occur
- Continuously improve surveillance strategies by applying new methods or techniques

Surveillance Throughout the Lifecycle



Quality Management Maturity (QMM)

Recent Context

- Drug Shortages: Root Causes and Potential Solutions, published in October 2019, examines the underlying factors responsible for drug shortages and recommends enduring solutions.
- The report identifies three root causes for drug shortages:
  1) Lack of incentives for manufacturers to produce less profitable drugs;
  2) ***The market does not recognize and reward manufacturers for "mature quality systems" that focus on continuous improvement and early detection of supply chain issues;*** and
  3) Logistical and regulatory challenges make it difficult for the market to recover from a disruption.
- The report also recommends enduring solutions:
  1) Creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
  2) ***Developing a rating system to incentivize drug manufacturers to invest in QMM for their facilities;*** and
  3) Promoting sustainable private sector contracts (e.g., with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.


Quality Management Maturity
Planning
Quality Management System
Performance Management/Continual Improvement
Quality Metrics
Quality Culture
Manufacturing Strategy and Operations
Predictive Analytics
Customer Experience
Workforce Management
Risk Management
Supply Chain Management
Management Review/Responsibility
Safety, Environment and Regulatory Compliance

Achieving QMM

- A quality management system (QMS) is a collection of business processes needed to consistently implement and maintain quality product in the marketplace
- A basic QMS is generally reactive, collect general/non-specific metrics, and are focused on Current Good Manufacturing Practice (CGMP) compliance
- A stronger, more mature QMS enables ***sustainable compliance***
  - Focus on performance and continual improvement, especially outcomes and metrics that impact the patient
  - Use data-driven approaches (e.g., predictive analytics) to reduce quality issues that lead to complaints, shortages, and adverse events
  - Quality Metrics programs and statistics are part of a mature QMS
- FDA has identified the need for a system to measure and rate a drug manufacturing facility's QMM, and a firm's ability to deliver high-quality drug products reliably and without disruption
  - Incentivize improved QMS by rewarding facilities that achieve a high degree of QMM
  - Provide transparency into the market for purchasers
  - Reduce the likelihood of quality problems that can lead to drug shortages by improving robustness of QMS

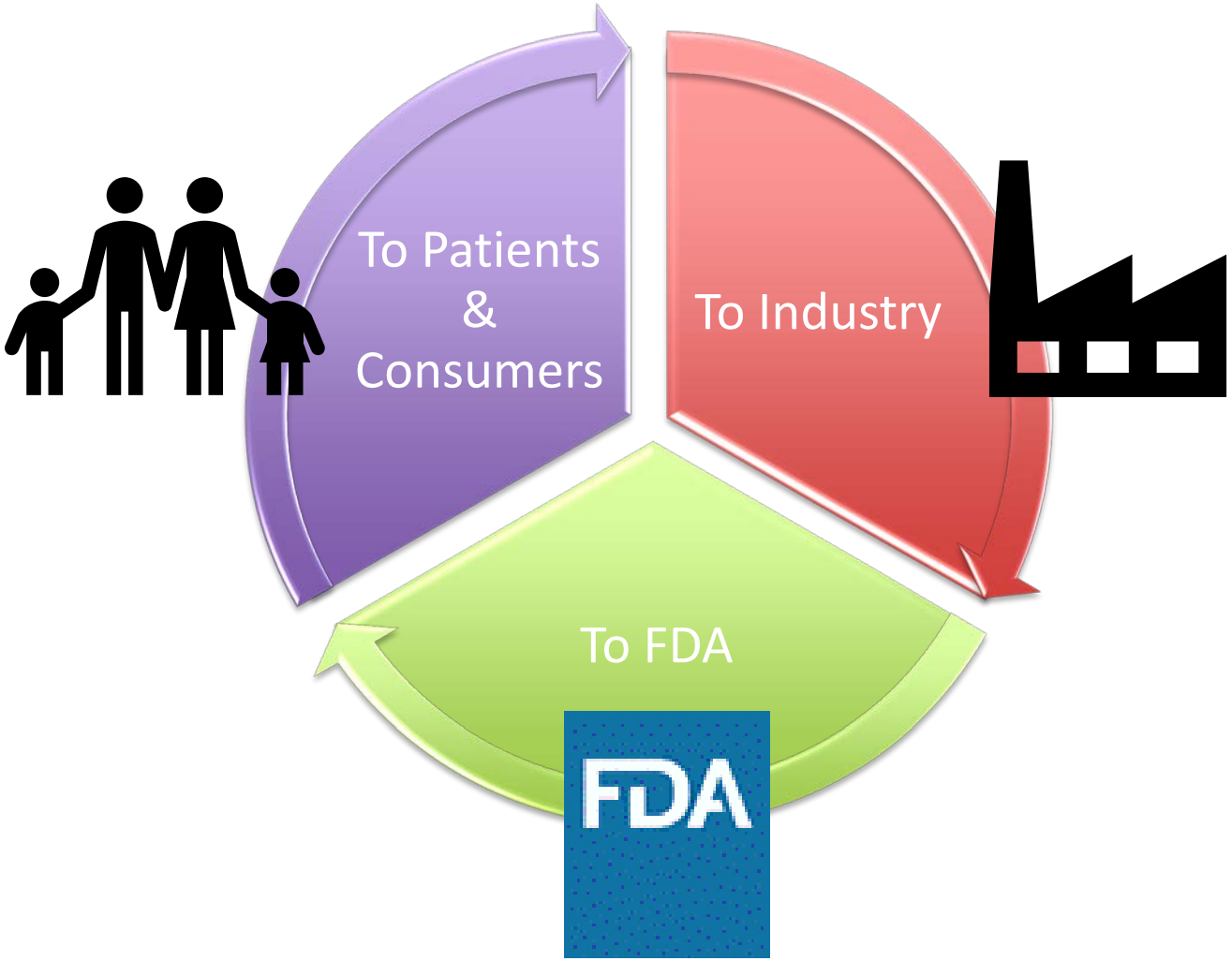
Steps to Achieving QMM

- QMM can be thought of as a measure of the consistency, reliability, and robustness of business processes established and maintained to achieve quality policies and objectives, including a focus on continual process and system improvement.

What does QMM Look Like?

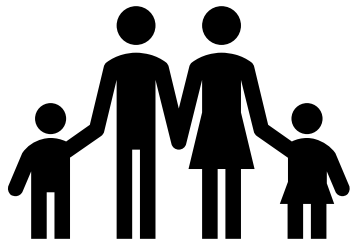
- Manufacturers and those with oversight and controls over manufacturing take ownership for quality:
  - Management sets the tone of commitment to quality
  - Invest in people
  - Organizational objectives drive quality
  - Quality systems shape culture
  - Focus on innovation and continual improvement
  - Move to performance-based quality management
  - **Robust metrics program with a focus on analytics**
  - Include risk management plans and forecasting to ensure reliability of supply

QMM is Important



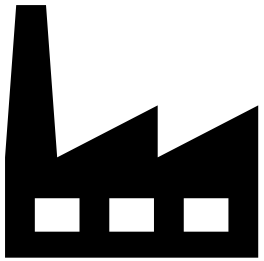
Why is QMM Important *to Patients and Consumers*?

- More reliable access to important drug products
  - Commitment to continual improvement by industry leads to more robust manufacturing processes
    - Fewer recalls
    - Fewer quality-related drug shortages



Why is QMM Important *to Industry*?

- Important element of oversight and controls over the manufacture of drugs to ensure quality (section 501 FD&C Act)
- Fewer recalls and improved corporate image
- Enables continual improvement of
  - process performance
  - product quality
  - pharmaceutical quality system
- Leads to quality system efficiencies, cost savings and regulatory flexibility



Why is QMM Important *to FDA*?

- Additional quantitative and objective insight into the state of quality for products and facilities
- Enhance risk-based allocation of surveillance tools
- Improve effectiveness of inspections
- Help to identify factors leading to supply disruption

Next Steps for QMM

- 2 FRNs published on Oct 16, 2020
  - Quality Management Maturity for Finished Dosage Forms Pilot Program (QMM FDF Pilot Program) – open to domestic manufacturers of drug products marketed in the US
    - Docket No. FDA-2020-N-2031
  - Quality Management Maturity for Active Pharmaceutical Ingredients Pilot Program (QMM API Pilot Program) – open to foreign manufacturers of API used in drug products marketed in the US
    - Docket No. FDA-2020-N-2018
- FDA seeks facilities to participate thru Nov 30, 2020
  - Voluntary
  - Up to 9 sites will be selected for each pilot program
- QMM appraisals will be conducted by a 3rd party
  - QMM FDF Pilot Program: Pacific Force Consulting Group, LLC (partnering with Booz Allen Hamilton, Inc)
  - QMM API Pilot Program: Shabas Solutions, LLC

Eligibility for Pilot Participation

- The company must be in good compliance standing (No Action Indicated or Voluntary Action Indicated final classification from FDA inspection within the last 5 years)
- While participating in the QMM Pilot Program, the company must agree to:
  - Assessments conducted by a contractor identified by FDA as having the expertise to assess QMM accompanied by FDA staff
  - Collect and submit developed metric data and provide it to FDA and the contractor prior to the assessment
  - Be available for real-time consultations with the contractor and FDA

QMM and Quality Metrics

- Quality metrics are a key aspect of a mature QMS (using data-driven approaches to reduce quality issues)
- Any assessment conducted to assess a facility's QMM would necessarily be an evaluation at a point in time
- Quality metrics data would be important to provide information about the quality of the facility and manufacturing process performance on an ongoing basis and in between on-site assessments

Take Aways

- Both strong metrics and quality culture programs are part of quality management maturity
- Current research indicates quality metrics and quality culture programs are a good business practice and an important element of modern pharmaceutical manufacturing
- OQS continues to engage stakeholders and support related academic research. Our goal is to keep all sites in compliance and all products available for the patient
- **OQS monitors the state of quality for sites and products so every dose is safe and effective, free of contamination and defects and patients can be confident in their next dose**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